

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

ANNE DE LACOUR, ANDREA WRIGHT,
and LOREE MORAN individually and on
behalf of all others similarly situated,

Plaintiffs,

v.

COLGATE-PALMOLIVE CO., and
TOM'S OF MAINE INC.,

Defendants.

16 Civ. 8364 (RA)(AJP)

**REPLY IN SUPPORT OF THE MOTION TO STAY OF DEFENDANTS
COLGATE-PALMOLIVE CO. AND TOM'S OF MAINE, INC.**

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Defendants submit the following reply in further support of their Motion to Stay:¹

I. INTRODUCTION

In their opposition brief, Plaintiffs essentially concede that this Court should stay the case pursuant to the primary jurisdiction doctrine and pending further guidance from the FDA regarding the definition of “natural.” While Plaintiffs claim that the Request cannot serve as the basis to stay the case because the Request addresses “natural” labeling in food products, Plaintiffs do not – and cannot – dispute that the FDA’s forthcoming guidance will be instructive in this case. Indeed, Plaintiffs’ own Complaint relies on current FDA guidance related to food products to support its claims. Plaintiffs cannot use the FDA’s guidance as both a sword and a shield, relying on it when it supports their position, but attempting to disclaim it when it is not convenient. And since Plaintiffs cannot deny that the FDA’s guidance would be instructive in this case, it is appropriate for this Court to stay this case pending that guidance.

Moreover, Plaintiffs rely almost exclusively on cases decided before the FDA announced the Request in November 2015, which cases offer little support for denying a stay now that it is clear that the FDA is in fact taking action to address the issues that are central to this case. As discussed in Defendants’ opening memorandum, courts within this district and throughout the country have stayed similar litigation challenging “natural” claims since the FDA issued the Request and in light of the upcoming guidance. The result should be the same in this case and Defendants respectfully request that this Court grant their motion for a stay.

¹ Unless stated otherwise, all emphasis is supplied and all internal citations and quotations are omitted from all quoted material herein. In addition, all capitalized terms used herein have the same meaning as given to them in Defendants’ opening memorandum. See generally Mem. (Dkt. No. 33).

II. ARGUMENT

A. Plaintiffs Have Conceded That FDA Guidance Regarding The Term “Natural” In Food Products Would Be Instructive To This Court’s Analysis In This Case

In their opposition brief, Plaintiffs repeatedly claim that the FDA’s Request cannot provide the basis for this Court’s invocation of the primary jurisdiction doctrine because the Request relates to the use of the term “natural” in the labeling of food products and not personal care and oral care products. See Opp. (Dkt. No. 35) at 1-3, 4-5. Notably, however, Plaintiffs do not dispute that the FDA’s pending guidance relating to the labeling of food products as “natural” would be instructive in this case. See id. at passim.²

Nor could they reasonably make such an argument, as Plaintiffs repeatedly rely upon FDA guidance related to food products in asserting that Tom’s products are purportedly not “natural.” See First Am. Compl. (Dkt. No. 8) ¶¶ 23, 25, 27(b)-(c), 27(l). For example, Plaintiffs quote from the FDA’s food labeling guidance, including the definition of “natural” as meaning “nothing artificial or synthetic . . . has been included in, or has been added to, a food that would not normally be expected to be in the food.” See First Am. Compl. (Dkt. No. 8) ¶ 25 (citing Food Labeling, 58 Fed. Reg. 2302). Plaintiffs also cite FDA organic regulations identifying some of the challenged ingredients, including ascorbic acid, glycerin, and xanthan gum, as “synthetic.” See id. ¶¶ 27(b)-(c), 27(l) (citing 7 C.F.R. 205.605(b) (listing non-agricultural substances allowed as ingredients in or on processed products labeled as “made with organic (specified ingredients or food group(s))”); 7 C.F.R. 205.603(a)(12) (listing synthetic substances allowed for use in organic livestock production)).

² Plaintiffs’ claim that if Defendants’ motion were granted the case would somehow be stayed “indefinitely” is hyperbolic. See, e.g., Opp. (Dkt. No. 35) at 1-2, 5. In reality, the FDA closed its Request for information and comments regarding use of the term “natural” in May 2016, a necessary step that will inform the FDA’s guidance, and seems determined to address the “natural” labeling issue in a reasonable time. See Mem. (Dkt. No. 33) at 3, 9.

Plaintiffs cannot rely on FDA regulations and guidance related to food products when they support Plaintiffs' claims but disavow them when they become inconvenient. See, e.g., Opp. (Dkt. No. 35) at 4-5; First Am. Compl. (Dkt. No. 8) ¶ 25. In light of Plaintiffs' prior reliance on FDA guidance relating to food products, there is no reason to believe that the FDA's forthcoming guidance regarding the use of "natural" in food labeling would not be instructive in this case. See In re KIND LLC "Healthy and All Natural" Litig., 209 F.Supp.3d 689, 693-97 (S.D.N.Y. 2016) (addressing "natural" labels); Coyle v. Hornell, 2010 WL 2539386, at *3-5 (D.N.J. 2010) (same).

B. Astiana Supports Defendants' Motion to Stay

Contrary to Plaintiffs' assertions, the Ninth Circuit's decision in Astiana v. Hain Celestial Grp., Inc., 783 F.3d 753 (9th Cir. 2015) in no way refutes Defendants' argument that this Court should stay the action under the primary jurisdiction doctrine. See Mem. (Dkt. No. 33) at 8. In Astiana, the Ninth Circuit held that the district court did not err in invoking the primary jurisdiction doctrine based on a belief that "new guidance" regarding "natural" would be "forthcoming" in response to "a flurry of litigation over food labeling." Astiana, 783 F.3d at 761.³ The Ninth Circuit reached this decision before the FDA actually took up the "natural" issue. See id. That the district court, on remand, declined to stay the case does not undermine the Ninth Circuit's determination that a stay under the primary jurisdiction doctrine may be appropriate where, as here, guidance from the FDA is likely to be forthcoming. See id. In fact, other cases have cited Astiana with approval in staying "natural" related cases under the doctrine

³ The district court in Astiana originally dismissed the case pursuant to the doctrine of primary jurisdiction. See Astiana, 783 F.3d at 756-57. The Ninth Circuit held that although the district court properly invoked primary jurisdiction, it erred in dismissing, rather than staying, the case, and remanded to allow the district court to consider whether a stay would be appropriate. See id. at 761-62.

of primary jurisdiction. See, e.g., In re KIND LLC, 209 F.Supp.3d at 693-94; Forsher v. J.M. Smucker Co., 2016 WL 5678567, at *2 (E.D.N.Y. 2016).

Furthermore, in denying the motion to stay, the Astiana district court relied primarily on the fact that the FDA “expressed no interest in the subject matter of the litigation” and that “formal referral [to the FDA] would be futile.” See Astiana Order (Dkt. No. 36-1) at 2-3.⁴ In other words, when the district court decided the motion to stay in October 2015, the FDA had not yet announced the Request for information and comments regarding use of the term “natural.” Compare id., with Mem. (Dkt. No. 33) at 1 (noting FDA announced Request in November 2015). Because the district court in Astiana originally dismissed the case under the doctrine of primary jurisdiction based, in part, on the belief that FDA guidance would be forthcoming, it is not clear that the district court would have denied the motion to stay had the FDA “expressed [an] interest” to issue guidance regarding use of the term “natural” a month earlier. See Mem. (Dkt. No. 33) at 8 (citing Astiana, 783 F.3d at 761).⁵ Because the FDA has now indicated that it will be issuing such guidance, a stay pending that guidance is appropriate. See id. at 1, 3 (citing cases where courts stayed actions pending FDA guidance regarding use of the term “natural”).

⁴ As Plaintiffs note, the Astiana district court stayed the case on alternative grounds. See Opp. (Dkt. No. 35) at 3 n.2.

⁵ Moreover, the basis for the Ninth Circuit’s remand, including whether a stay would “needlessly delay the resolution of claims” and “whether the parties would be unfairly disadvantaged” by a stay, are factors considered by courts within the Ninth Circuit in deciding whether to stay a case pursuant to the primary jurisdiction doctrine. See Kane v. Chobani LLC, 645 Fed. Appx. 593, 594 (9th Cir. 2016) (concluding that “resolution of this action will not be needlessly delayed” if action stayed under doctrine of primary jurisdiction); Opp. (Dkt. No. 35) at 3. The Second Circuit, however, has cautioned against weighing the potential for delay too heavily because “the Supreme Court has never identified judicial economy as a relevant factor” in applying the primary jurisdiction doctrine. See Ellis v. Tribune Television Co., 443 F.3d 71, 90 (2d Cir. 2006). Plaintiffs, moreover, have not argued that they would be prejudiced by a stay pending guidance from the FDA. See Opp. (Dkt. No. 35) at passim.

**C. Plaintiffs' Opposition Lacks Relevant Authority To Establish
That The Primary Jurisdiction Doctrine Should Not Apply**

Plaintiffs argue that Defendants rely on inapposite case law in support of their Motion to Stay, and mischaracterize as “baseless” Defendants’ request that this Court apply the primary jurisdiction doctrine. See Opp. (Dkt. No. 35) at 3-4. In all but one instance, however, Plaintiffs fail to cite cases decided after the FDA announced its Request in November 2015.⁶ See, e.g., id. at 4 (citing cases decided before November 2015). Other courts have, unsurprisingly, found such cases to be of little help to parties opposing the application of the primary jurisdiction doctrine based upon the FDA’s Request. See, e.g., Forsher, 2016 WL 5678567, at *2 (rejecting citation to cases decided before the FDA’s announcement and noting that “[e]ach of these courts denying a stay found significant that the FDA had declined to promulgate a rule on which products could be labeled ‘natural’”).

In addition, Plaintiffs’ attempt to weigh the factors set forth in Ellis against applying the primary jurisdiction doctrine fails. See Opp. (Dkt. No. 35) at 5-9. For the first factor (i.e., whether the matter involves an issue better left to the FDA rather than the courts), Plaintiffs claim this Court need only decide “whether or not Defendants’ statements that their products are ‘natural’ are misleading to a reasonable consumer in light of the ingredients the products contain.” See id. at 6. Plaintiffs ignore the fact that to answer this question, this Court will need to determine whether Tom’s products are “natural” based on, among other things, the chemical

⁶ Plaintiffs cite Bautista v. CytoSport, Inc., 2016 WL 7192109, at *3 (S.D.N.Y. Dec. 12, 2016) for the general proposition that the doctrine of primary jurisdiction has a “narrow scope.” See Opp. (Dkt. No. 35) at 5. In Bautista, the court denied a request to stay or dismiss a case under the primary jurisdiction doctrine because the FDA had “clearly set forth” the standard governing the dispute at issue. See Bautista, 2016 WL 7192109, at *3. Bautista, therefore, is inapplicable where, as here, the FDA has not defined “natural” for any products and there is no clear FDA standard upon which this Court can rely. See Forsher, 2016 WL 5678567, at *2 (noting that the FDA has not adopted a formal definition of the term “natural”).

makeup and processing of their ingredients. See First Am. Compl. (Dkt. No. 8) ¶ 23 (“Defendants’ representations that their Products are ‘natural’ are false and misleading because each of the Products contains at least one, and in most instances, several, ingredients that are synthetic or highly chemically processed.”). The FDA is better equipped to determine what type of products and ingredients should qualify as “natural.” See Mem. (Dkt. No. 33) at 4-5 (citing Forsher, 2016 WL 5678567, at *2; Coyle, 2010 WL 2539386, at *4-5).⁷

As for the second Ellis factor, whether the question at issue is particularly within an agency’s discretion, Plaintiffs cannot credibly argue that the mere fact that there are sources other than the FDA that can be consulted for the definition of “natural” weighs against invoking primary jurisdiction. See Opp. (Dkt. No. 35) at 7. Other sources may help this Court determine the definition of “natural,” but Congress empowered the FDA to prohibit labels that are “false or misleading in any particular.” See Mem. (Dkt. No. 33) at 6 (citing 21 U.S.C. § 362). Therefore, determining whether an ingredient or product is “natural” is “particularly within the FDA’s discretion” and this factor supports a stay of this case under the primary jurisdiction doctrine. See id. at 6 (citing In re KIND LLC, 209 F.Supp.3d at 695).

Similarly, Plaintiffs suggest that the remaining Ellis factors (i.e., a substantial danger of inconsistent rulings and a prior application to the FDA) weigh against a stay because the Request relates to food products and not the personal care and oral care products at issue here.⁸ See Opp.

⁷ Plaintiffs also argue that this Court should ignore Defendants’ cited cases, where courts invoked the primary jurisdiction doctrine to stay similar labeling claims related to “natural” products, because those cases involved “food” ingredients and “complex chemical considerations.” See Opp. (Dkt. No. 35) at 6. Plaintiffs fail to explain why “food” ingredients are inherently more complex than the ingredients at issue here, nor do they explain why the FDA’s guidance, even if targeted at food products, would not be instructive in this case. See id.

⁸ As noted in Defendants’ opening memorandum, the FDA received comments from industry groups and consumers addressing the possibility of overlap between use of the term “natural” in food products and in personal care and oral care products, an indication that the

(Dkt. No. 35) at 7-8. As noted above, this position cannot be reconciled with Plaintiffs' reliance in their Complaint on FDA guidance related to food products. See disc. supra at 2-3.

In short, Plaintiffs have provided no basis for their argument that the primary jurisdiction doctrine should not apply in this case and that the case should not be stayed pending the FDA's forthcoming guidance.

III. CONCLUSION

For the reasons stated above and in Defendants' Memorandum of Law, Defendants respectfully request that this Court grant Defendants' Motion to Stay.

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Respectfully submitted,

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FDA's guidance may have some applicability to personal care and oral care products. See Mem. (Dkt. No. 32) at 8 n. 3. Plaintiffs do not address these comments, nor do they cite to any FDA communications made after the announcement of the Request where the FDA stated that the Request and pending guidance would not also pertain to personal care and oral care products. See Opp. (Dkt. No. 35) at 7-9.